

### REMARKS/ARGUMENTS

Claims 1-12 and 24-25 are currently pending. Claim 25 is new. Claim 1 has been amended. Review and reconsideration on the merits are requested in view of the following comments.

Claims 1-11 and 24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Patel et al. US 2003/0215496. According to the Office action, Patel teaches compositions or solid carrier particles containing a skeletal muscle relaxant, such as cyclobenzaprine, wherein the composition can be in the form of a capsule, tablet, pellet, or bead. Furthermore, Patel et al. discloses that the dosage form can be immediate release, pulsatile release, controlled release, extended release, delayed release, targeted release, synchronized release or targeted delayed release. Moreover, Patel discloses that pH-independent coatings such as ethyl cellulose may be used to provide extended release. Applicants respectfully submit that Patel fails to anticipate or render obvious the claims of the present application. Accordingly, applicants respectfully request that the rejection be withdrawn.

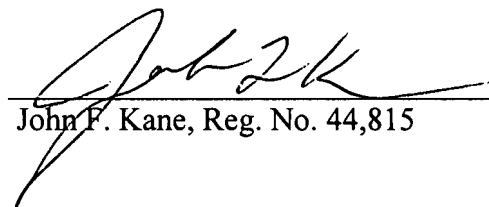
Applicants respectfully submit that Patel fails to disclose or suggest the pharmaceutical dosage form set forth in the claims of the pending application. Patel broadly discloses solid carriers for improved delivery of the active ingredients pharmaceutical compositions and provides sweeping reference to all types of actives, coatings and release profiles. Muscle relaxants such as cyclobenzaprine are among a laundry list of other drug substances which may be used in the pharmaceutical compositions described in the reference. The reference fails to provide any teaching or suggestion that would lead one of ordinary skill in the art to the composition set forth in the claims of the pending application. Even if one of ordinary skill in the art were to elect cyclobenzaprine from the long list of actives and elect an extended release coating containing a water insoluble polymer, there is simply insufficient direction in Patel to lead one to a multi-particulate pharmaceutical dosage form which provides a modified release profile and contains a population of extended release beads having the profile set forth in the claims of the pending application. Moreover, claims of the pending application are not anticipated by Patel because the reference fails to disclose each and every limitation of the claim, namely the specified release profile. The release profile is a functional aspect of the claim which must be afforded weight as any other limitation in the claim.

In conclusion, Patel cannot anticipate the claims of the present application because the disclosure therein fails to place the public in the possession of dosage forms as set forth in the claims of the pending application. Accordingly, applicants respectfully request that the rejection be withdrawn.

Claims 1-4, 6-11 and 24 stand rejected under 35 U.S.C. §102(b) as being anticipated by Meadows et al. US 2003/0099711. Meadows fails to anticipate for the same reasons as set forth above with respect to the Patel reference. Meadows discloses a wide range of actives and pharmaceutical compositions that can be used to provide various release profiles but fails to provide any specific teachings with respect to cyclobenzaprine and extended release beads in a multi-particulate pharmaceutical dosage form as set forth in the claims of the pending application. Furthermore, Meadows et al. fails to disclose or suggest the release profile set forth in the claims. As with Patel, one of ordinary skill in the art reading the Meadows reference would not be in possession of the dosage form set forth in claims of the pending application. Accordingly, applicants respectfully request that the rejection be withdrawn.

In view of the foregoing, it is respectfully submitted that all of the pending claims are in condition for allowance and favorable action on the merits is requested. Any questions concerning this application may be directed to applicant's undersigned attorney at the telephone number indicated below.

Respectfully submitted,



John F. Kane, Reg. No. 44,815

THOMPSON HINE LLP  
2000 Courthouse Plaza NE  
10 West Second Street  
Dayton, Ohio 45402-1758  
(937) 443-6816